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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,585	08/28/2003	Diane Thibeault	13/082-1-D1	7451

28513 7590 06/06/2006

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,585	THIBEAULT ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3 and 5* is/are allowed.

6)☒ Claim(s) *4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignment attached*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/2005 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 4 is rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the abstract by Steinkuhler et al (cioted on IDS). Claim 4 is drawn to an isolated polypeptide consisting of an amino acid sequence 90% identical over its length compared to SEQ ID NO: 4 or 10. According to applicant's specification, SEQ ID NO:10 is HCV NS2/3 residues 904-1206. Steinkuhler teaches an isolated protein containing residues 907-1206, and teaches that this region is a minimal catalytic entity for the protease. Although Steinkuhler does not teach the sequence of the HCV protein used, there is reason to believe that it is at least 90% identical to SEQ

ID NO:10. The authors later disclose that they used the HCV J isolate (see as evidence Pallaoro et al, Journal of Virology 75:9939-9946, October 2001). The 907-1206 region of HCV J strain is at least 94% identical to SEQ ID NO: 10 (see the attached alignment). Therefore, there is reason to believe that the reference inherently anticipates the invention as claimed. Alternatively, the reference teaches that the region 907-1206 is essential for protease catalytic activity, and teach that the protease can be isolated. It would have been a matter of routine experimentation to determine the modulated growth conditions suggested as suppressing self cleavage, and to choose any known strain of HCV for the source of the protease. Since known strains of HCV (including HCV J) would fall within the required homology parameters, it is concluded that the invention as a whole was at least prima facie obvious, if not anticipated by the reference.

Allowable Subject Matter

Claims 3 and 5 remain allowed, because the prior art does not teach or suggest the specific amino acid sequences recited in these claims, or provide motivation to substitute amino acids within the previously known HCV polyprotein sequences to reach the specific recited sequences.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/30/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

Sequence alignment

gi|221611|dbj|BAA14233.1| unnamed protein product [Hepatitis C virus]
Length=3010 (HCV J Polyprotein)

Score = 530 bits (1364), Expect = 2e-154
Identities = 286/303 (94%), Positives = 297/303 (98%), Gaps = 0/303 (0%)

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Seq 10 1    AGITKVPYFVRAQGLIRACMLVRKAAGGHYVQMAFMKLAALTGTYVYDHLTPLQDWAHAG  60
            AGIT+VPYFVRAQGLIRACMLVRK AGGHYVQMAFMKLAALTGTYVYDHLTPL+DWAHAG
HCV J  904 AGITRVPYFVRAQGLIRACMLVRKVAGGHYVQMAFMKLAALTGTYVYDHLTPLRDWAHAG  963

Seq 10 61   LRDLAVAVEPVIFSDMEVKIITWGADTAACGDIISGLPVSARRGREILLGPADNFEGQGW  120
            LRDLAVAVEPV+FSDME K+ITWGADTAACGDIISGLPVSARRG+EILLGPAD+F  QGW
HCV J 964   LRDLAVAVEPVVFSDMETKLITWGADTAACGDIISGLPVSARRGKEILLGPADSFGEQGW  1023

Seq 10 121  RLLAPITAYSQQTRGLLGCIITSLTGRDKNQVEGEVQVVSTATQSFLATCVNGVCWTVFH  180
            RLLAPITAYSQQTRGLLGCIITSLTGRDKNQV+GEVQV+STATQSFLATCVNGVCWTV+H
HCV J 1024  RLLAPITAYSQQTRGLLGCIITSLTGRDKNQVDGEVQVLSTATQSFLATCVNGVCWTVYH  1083

Seq 10 181  GAGSKTLAGPKGPITQMYTNVDQDLVGWQAPPGARSMTPCTCGSSDLYLVTRHADVIPVr  240
            GAGSKTLAGPKGPITQMYTNVDQDLVGW APPGARSMTPCTCGSSDLYLVTRHADV+PVR
HCV J 1084  GAGSKTLAGPKGPITQMYTNVDQDLVGWPAPPGARSMTPCTCGSSDLYLVTRHADVVPVR  1143

Seq 10 241  RGDSRGSLLSPRPVSYLKGSSGGPLLCPSGHAVGIFRAAVCTRGVAKAVDFIPVESMET  300
            RRGDSRGSLLSPRP+SYLKGSSGGPLLCPSGH VGIFRAAVCTRGVAKAVDFIPVESMET
HCV J 1144  RRGDSRGSLLSPRPISYLKGSSGGPLLCPSGHVVGIFRAAVCTRGVAKAVDFIPVESMET  1203

Seq 10 301  TMR  303
            TMR
HCV J 1204  TMR  1206
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